

exposing a representative reference example of the package incorporating the authenticating agent to the given effective amount of radiation;

spectroscopically analyzing the irradiated representative reference example to obtain the characteristic a spectral response for the irradiated representative reference example;

exposing at least a portion of a package to be authenticated to the given effective dosage of radiation;

spectroscopically analyzing the irradiated package portion to obtain a spectral response for the irradiated package portion; and

comparing the spectral response for the irradiated package portion to the characteristic spectral response for the irradiated representative reference example to determine whether the package to be authenticated is authentic.

Support for these amendments is found in the application as originally filed.

REMARKS

Applicant respectfully requests entry of the present amendment and consideration of these remarks. Claims 1, 3-7, 9-10, 13-15, and 17-37 remain in this application. Claims 1, 3, 7, 9, and 22 are amended. Claims 2 and 8 are cancelled, their subject matter being incorporated into the claims from which they depended. Applicant respectfully traverses the rejections as conceivably applied to the pending claims.

Attached is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned "Version with Markings to Show Changes Made."

I. Drawing Objections

The drawings were objected to under 37 C.F.R. §1.83(a). Unless advised otherwise in the next Office Action, it will be assumed that this objection was made because the nature of the subject matter sought to be patented admits of illustration by a drawing without the

drawing being necessary for the understanding of the subject matter – that is, the drawing is desired merely to facilitate the understanding of the subject matter disclosed.

Accordingly, Applicant has amended the drawings to add Figures 3 and 4. Applicant respectfully requests the Examiner's approval of the added drawing and withdrawal of the objection.

II. Non-Art Rejections

Independent claim 22 has been rewritten to overcome the indefiniteness rejection under 35 U.S.C. §112, second paragraph. The term “representative reference example” replaces the former term “representative reference sample” to clarify that the representative reference example does not need to be in or from the “package.” To determine whether the package to be authenticated is authentic, the comparison of the spectral response for the irradiated package portion to the characteristic spectral response for the irradiated representative reference example may be accomplished, for example, as discussed in the Application on page 24, lines 14-15.

Claims 17-20 and 23-37 depend from independent claim 22.

Dependent claim 36 was also rejected under 35 U.S.C. §112, second paragraph, as indefinite for the recitation of “100 ppm.” Applicant respectfully traverses this rejection. Claim 36 recites “from about 100 ppm to about 5 weight percent based on the weight of the packaging material.” One of skill in the art would clearly recognize from this claim recitation that the lower end of the range for the amount of dosimetric agent is the ratio of about 100 weight parts dosimetric agent to one million weight parts of packaging material -- and further that the upper end of the range for the amount of dosimetric agent is about 5 percent of the weight of the packaging material. These amounts for the end points of the range are readily understandable. There is no indefiniteness presented by these end points of the range because the upper range limit of about 5 percent will *always* be above the lower range limit of about 100 ppm. Further, an applicant “may use . . . any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought. . . [A] claim may not be rejected

solely because of the type of language used to define the subject matter for which patent protection is sought." MPEP 2173.01 (emphasis added).

III. Rejections Based on Regulla

As previously presented, claims 1-2, 4-8, 10, 13-15, 17-23, and 25-26 were rejected under 35 U.S.C. § 102(b) as anticipated by Regulla et al, "Dosimetry by ESR Spectroscopy of Alanine," Int. J. Appl. Radiat. Isot., Vol. 33, pp. 1101-1114 (1982) ("Regulla"). Further, dependent claims 3, 9, 24, and 27-37, as previously presented, were rejected under 35 U.S.C. §103(a) as obvious in view of Regulla. Applicant respectfully traverses these rejections.

Regulla discloses a dosimeter based on the electron spin analysis of radiation-induced free radicals in alanine. (Regulla, page 1114 Summary.) The Regulla dosimeter consists of pellets made of up to 90 weight % alanine bound in paraffin. (Regulla, page 1104 Sample Preparation.)

To anticipate a claim, the applied reference must teach each and every element of the claim. MPEP §2131. In the present case, however, Regulla fails to disclose or even suggest either a package in which "an effective amount of authenticating agent" is "incorporated into the one or more packaging materials," as recited in amended claim 1, or a method of making a package by "incorporating an authenticating agent into a packaging material," as recited by amended independent claim 7. This is at least because Regulla binds alanine in *paraffin* to form a *dosimeter*, and therefore fails to disclose or suggest either of the above cited claim recitations regarding incorporation of authenticating agent into a packaging material.

Regulla also fails to disclose or even suggest the step of "comparing . . . to determine whether the package to be authenticated is authentic" as recited in independent claims 21 and 22 (as amended). Regulla fails to disclose or suggest anything regarding a determination of whether a package is "authentic," for example, by determining whether a package is counterfeit or from a source different than the source of the authentic package.

To the contrary, Regulla teaches *calibration* of a dosimeter system – not the *authentication* of a package. Regulla teaches the "direct dose calibration of the ESR [electron

spin resonance] spectrometer" by using a subject ESR spectrometer to take the ESR scale readings of the "standard sample" *dosimeters* (i.e., dosimeters having known ESR scale readings after exposure to known amounts of radiation). The readings from the subject ESR spectrometer can then be calibrated to the known ESR scale readings to provide a reliable measurement of the amount of radiation absorbed by an exposed dosimeter. (See Regulla page 1103, right column to page 1104, left column.) This calibration technique suggest nothing about authenticating a package (i.e., determining whether the package is counterfeit).

The rejected dependent claims 2, 4-6, 8, 10, 13-15, 17-20, 23, and 25-26 have recitations additional to those of the independent claims that were rejected over Regulla, and are therefore further patentable over Regulla.

With respect to dependent claims 3, 9, 24, and 27-37, which were rejected as obvious in view of Regulla, Applicant respectfully submits that a *prima facie* case of obviousness has not been established necessary to shift the burden of rebuttal to Applicant. A *prima facie* obviousness case requires that *all* of the claim recitations be suggested by the prior art. MPEP §2143.03. Further, the mere fact that a reference could be modified does not render the modification obvious; the prior art must suggest the desirability of the modification. §MPEP 2143.01. In this case, Applicant respectfully submits that neither requirement has been met with respect to these dependent claims.

There is no cited authority supporting the proposed reason for modifying Regulla as suggested by the Office Action as "obvious variation in design." At least for this reason, Applicant respectfully submits that a *prima facie* case of obviousness has not been established. "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with. The need for specificity pervades this authority." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (cites omitted). The factual question of motivation to combine cannot be resolved on "subjective belief and unknown authority." *Id.* at 1434. The best defense against improper hindsight-based obviousness is the requirement for a showing of the

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teaching or motivation to combine prior art references. *In re Dembicza*k, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Further, to the extent that the Examiner is relying upon common knowledge or well-known prior art to establish that it "is well known in the art to use such agents as the sugar in the food or beverage product for testing the product," as stated on page 5 of the most recent Office Action, Applicant respectfully requests that the Examiner supply references to support that position. *See* MPEP 2144.03.

IV. Regulla Page 1112

The previously Office Action requested a copy of page 1112 of Regulla. It turns out that Regulla page 1112 is blank; accordingly, Applicant has not submitted a copy of it with this Response.

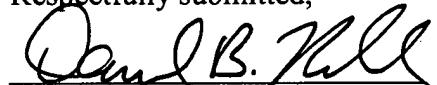
V. Conclusion

In view of the above amendments and these remarks, it is respectfully submitted that the present application is in condition for allowance. A notice to that effect is earnestly and respectfully requested.

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ATTACHMENT

Version with Markings to Show Changes Made

In the Claims:

Claims 1, 3, 7, 9, and 22 have been amended as follows:

1. (Twice Amended) A package comprising:

a product; and

one or more packaging materials enclosing the product, wherein an effective amount of authenticating agent is incorporated into the one or more packaging materials and package, wherein the authenticating agent is a substance that forms detectable free radicals upon irradiation.

3. (Amended) The package of claim 1 2, wherein the one or more packaging materials comprises a polymeric packaging film, said authenticating agent being incorporated in said film.

7. (Twice Amended) A method of making a package, comprising:

incorporating an authenticating agent into a packaging material component of the package as an in situ product marker; and

forming a package comprising the the packaging material, wherein the authenticating agent is a substance that forms detectable free radicals when exposed to ionizing radiation, said authenticating agent being present in a manner such that the free radicals provide a characteristic spectral response when subjected to a spectroscopic analysis capable of detecting free radicals in order to allow authentication of the package from said spectral response.

9. (Amended) The method of claim 7 8, wherein the packaging material comprises a polymeric packaging film, and wherein the authenticating agent is incorporated into said film.

22. (Amended) A method of authenticating a package comprising:

providing a package incorporating a given amount of one or more authenticating agents that upon exposure to a given effective dosage of radiation is capable of forming detectable free radicals having a characteristic spectral response;

exposing a representative reference example sample of the package incorporating the authenticating agent to the given effective amount of radiation;

spectroscopically analyzing the irradiated representative reference example sample to obtain the characteristic a spectral response for the irradiated representative reference example sample;

exposing at least a portion of a package to be authenticated to the given effective dosage of radiation;

spectroscopically analyzing the irradiated package portion to obtain a spectral response for the irradiated package portion; and

comparing the spectral response for the irradiated package portion to the characteristic spectral response for the irradiated representative reference example sample to determine whether the package to be authenticated is authentic.